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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/691,002

10/22/2003

Laurie B. Gower

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1657

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11/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/691,002	<b>Applicant(s)</b> GOWER ET AL.	
	<b>Examiner</b> David M. Naff	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,8,11,13,15,19-24,31,32,34 and 79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,8,11,13,15,19-24,31,32,34 and 79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/27/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

A response of 8/5/08 presented arguments and did not amend the claims.

Claims examined on the merits are 1-3, 5, 8, 11, 13, 15, 19-24, 31, 32, 34 and 79, which are all claims in the application.

5           The document listed on form PTO/SB/08B has been lined through and not considered since it does not have a publication date.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

10           A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15           Claims 1-3, 5, 8, 11, 13, 15, 24, 31 and 79 are rejected under 35 U.S.C. 102(a) as being anticipated by Olszta (Biomimetic Mineralization of Type-I Collagen) (R9 on 1449 of 5/12/04) or Olszta (Biomimetic Mineralization of Type-I Collagen) (R11 on 1449 of 5/12/04) or Olszta (Biomimetic Mineralization of Collagen for Nanostructured Composites (R27 on 1449 of 3/15/04).

20           The claims are drawn to an organic/inorganic composite comprising and organic fluid-swallowable fibrous matrix comprising fibers and interstitial spaces, and an inorganic mineral phase of amorphous or crystalline structure that coats and infiltrates each of the fibers, and is embedded in the interstitial spaces.

25           Olszta R9, R11 or R27 disclose mineralization of collagen by preparing a calcium chloride solution, addition of short chain acidic polymers (poly-L-aspartic acid and polyacrylic acid), addition of a collagen substrate, and vapor diffusion of ammonium carbonate. For example, see the 5<sup>th</sup> page of R9 and R27, and pages 15 and 16 of R11.

The mineralization of collagen as disclosed by Olszta R9, R11 or R27 produces a composite that is the same as presently claimed. The collagen of the R9, R11 or R27 has fibers and interstitial spaces as claimed, and the composite produced by Olszta R9, R11 or R27 inherently has an inorganic mineral phase of amorphous or crystalline structure that coats and infiltrates each of the fibers, and is embedded in the interstitial spaces. The calcium chloride solution, acidic polymer and ammonium carbonate of Olszta R9, R11 or R27 form a mineral precursor of Olszta R9, R11 or R27. The features of dependent claims are inherently contained by the composite produced as disclosed by Olszta R9, R11 or R27.

***Claim Rejections - 35 USC § 103***

Claims 19-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Liu (6,300,315 B1).

The claims require the composite to contain a biologically active agent.

Liu discloses producing a mineralized collagen membrane by adding calcium and phosphate ions to a collagen slurry (col 2, line 53 to col 3, line 21) to form precipitated calcium phosphate. A drug may be incorporated in the membrane (col 3, lines 57-65). Drugs include antibiotics, bone morphogenetic proteins, bone growth factors, skin growth factors, antiscarring agents and/or mixtures.

It would have been obvious to incorporate a biologically active agent when preparing the composite of Olszta R9, R11 or R27 to obtain the function of the agent as suggested by Liu incorporating a drug that is a biologically active agent in a mineralized collagen membrane.

***Claim Rejections - 35 USC § 103***

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 19-21 and 23 above, and further in view of Rhee et al.

The claim requires the biologically agent to be pendantly attached to the matrix.

Rhee et al is described above.

When incorporating a biologically active agent as suggested by Liu as above, it would have been obvious to attach the biologically active agent pendantly to a reactive group formed  
5 on the collagen of Olszta R9, R11 or R27 as suggested by Rhee et al rather than incorporating the agent in the collagen.

***Claim Rejections - 35 USC § 103***

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Connelly et al (6,995,013 B2).

10 Claim 32 requires the composite to comprise seeded cells.

Connelly et al disclose using collagen to form a cell-scaffold having five layers (col 13, lines 38-42) for producing tissue, and that bone structure contains osteons formed of lamellae (col 2, lines 24-37).

It would have been obvious to seed the collagen of Olszta R9, R11 or R27 with cells as  
15 suggested by Connelly et al to form tissue.

***Claim Rejections - 35 USC § 103***

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Song et al (5,418,222).

Claim 34 requires the matrix to comprise a film.

20 Song et al disclose a multiple layer collagen film having an adhesive between each layer for delivery of pharmaceuticals (col 5, lines 58-61).

It would have been obvious to provide the collagen of Olszta R9, R11 or R27 as a multiple layer film and adhere the layers together with an adhesive as suggested by Song et al when desiring the function of a multiple layer film.

### ***Response to Arguments***

The response urges that Olszta R27 is material presented at a Gordon Research Conference where there was a restriction that information presented was not for public use as shown by Exhibit A submitted with a previous amendment. However, while there was

5 restriction, the restriction prevented public use of information and prohibited recording of lectures, photography of side or poster material and printed reference to conference papers and discussions held. These restrictions do not require individuals to keep the information secret or confidential, and not convey the information to anyone else. The restriction does not prevent individuals at the conference from providing information obtained to others in a manner that is

10 not public such as in a private conversation. Individuals at the conference are the public, and in the absence of requiring the individuals to maintain information secret or confidential, *In re George* cited by the response does not apply since in this situation there was a policy of confidentiality, which is absent from the restrictions of the Gordon Research Conference. Also, the restrictions of the Gordon Research Conference, do not meet the requirement for keeping

15 secret set forth in MPEP 2132.

The arguments concerning the 37 CFR § 1.132 Declaration by co-inventor, Dr. Laurie B Grower, filed 12/26/06 is unpersuasive for the type of reasons set forth in a previous office action. The concept of the claimed invention is much broader than the specific process described in Olszta R9 and R27, and the declaration fails to establish that Dr. Douglas was also

20 involved in conceiving the specific procedures described by in Olszta R9 and R27. The declaration states the Dr. Douglas was not directly involved in the experiments described in Olszta R9 and R27. Conceiving a generic invention as claimed does not establish conceiving a specific species as described by in Olszta R9 and R27 within the scope of the generic invention.

An Exhibit B submitted with a previous amendment lists Douglas and Gower as investigators. However, the present invention contains Olszta and Wheeler as co-inventors in addition to Douglas and Gower. Additionally, Exhibit B does not disclose the specific embodiments of Olszta R9 and R27. This is not an In re Katz situation since the present  
5 invention is by co-inventors who are not authors.

The response urges that Connelly et al (filed 7/8/02) is antedated by 60/373,801 filed 4/18/02. However, the present invention as claimed is not described in 60/373,801, and 60/373,801 does not have support for the presently claimed invention.

### ***Conclusion***

10 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the  
15 THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

5 Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you  
10 would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/  
Primary Examiner, Art Unit 1657

15 DMN  
11/10/08